DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 1, 2014

Slater Endoscopy, LLC
% Craig Pagan
Regulatory Consultant
C2C Development, LLC
1135 W NASA Blvd., Suite 500
Melbourne, FL 32901

Re: K141058
Trade/Device Name: Slater Endoscopy Ensizor Endoscopic Scissors
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCZ
Dated: June 23, 2014
Received: June 25, 2014

Dear Craig Pagan,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141058

Device Name

Slater Endoscopy Ensizor Endoscopic Scissors

Indications for Use *(Describe)*

Slater Endoscopy Ensizor Endoscopic Scissors are designed to cut and dissect tissue during flexible endoscopic procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

(1) **Submitter's name, address, telephone number, a contact person and date summary was prepared:**

Slater Endoscopy, LLC
14000 NW 58 Ct.
Miami Lakes, FL 33014
Telephone: (305) 889-3350
Contact: Charles Slater
July 17, 2014

(2) **Name(s) of device:**

Proprietary/Trade Name:	Ensizor™ Endoscopic Scissors
Common Name:	Endoscope and/or Accessories
Classification Name:	Endoscope and Accessories (21 CFR 876.1500)
Classification Panel	Gastroenterology/Urology
Product Code:	OCZ
Regulatory Class:	II

(3) **Legally Marked Predicate Device to which the submitter claims substantial equivalence:**

The Ensizor™ Endoscopic Scissor is substantially equivalent to the Apollo Endosurgery Endoscopic Scissors (K090583).

(4) **Description of device(s):**

Ensizor™ Endoscopic Scissor

- Cat # ES-26165 2.6 mm Endoscopic Scissors x 165cm working length
- Cat # ES-26235 2.6 mm Endoscopic Scissors x 235cm working length

The above referenced Endoscopic Scissors are sterile, single use, non-electrocautery devices for soft tissue dissection during flexible endoscopic procedures. The devices are compatible with flexible endoscopes with a minimum channel diameter of 2.8 mm. The device cuts and dissects tissue during flexible endoscopic procedures. The device consists principally of an actuation handle and a flexible shaft body terminating in a pair of cutting scissors. The scissor blades function as standard scissors for mechanical cutting of sutures and tissue.

(5) **Statement of intended use:**

Slater Endoscopy Ensizor Endoscopic Scissors are designed to cut and dissect tissue during flexible endoscopic procedures.

(6) **Comparison of Technological Characteristics to Predicate Device:**

The Ensizor™ Endoscopic Scissors have the same technological characteristics as the predicate devices as described below:

- devices are designed to cut and dissect tissue during endoscopic procedures
- devices consists principally of an actuation handle and a flexible shaft body terminating in a pair of cutting Scissors
- scissors function just like standard scissors for mechanical cutting. By operating the handle, the Scissors open and close.

Differences:

The main difference between the Ensizor™ Endoscopic Scissor and the predicate device - Apollo Endosurgery Endoscopic Scissor (K090583) is that the Ensizor™ Endoscopic Scissors do not have an electrocautery function.

(7) **Performance Data:**

The following nonclinical testing was performed in order to evaluate the substantial equivalence of the Ensizor™ Scissors to the predicate devices:

- Operation in Tortuosity – each device shall open and close with the distal shaft of the device is formed into approximately a 20 cm or 8 in diameter circle.

  This test simulated operation of the device in a flexible endoscope. The results of the tests shows that the Ensizor™ Endoscopic Scissor is substantially equivalent to the predicate devices tested as they actuated as good as or better than the predicate devices in a tortuous path.

- Sample Cutting – Each device shall cut at least 10 times each of the following sample material:

  - LDPE Polyethylene Sheet

  The sample cutting test simulated the functionality of the Ensizor™ Endoscopic Scissor in cutting material. The results of the tests shows that the Ensizor™ Endoscopic Scissor is substantially equivalent to the predicate devices tested as they cut the materials tested as good as or better than the predicate devices.

Table 3
510(k) Summary - Testing Summary

Test	Ensizor™ Endoscopic Scissors Baseline	Ensizor™ Endoscopic Scissors Post 1 year Accelerated Aging	Ensizor™ Endoscopic Scissors Post 1 Transportation & Distribution Testing	Apollo Endosurgery Endoscopic Monopolar Scissors
Sample Size	15 – 235 cm 15 – 165 cm	15 – 235 cm 15 – 165 cm	15 – 235 cm 15 – 165 cm	1 – 235 cm
Operation in Tortuosity	All units passed	All units passed	All units passed	Unit had difficulty opening and closing in the tortuous configuration
Sample Cutting LDPE Polyethylene Sheet	All units Passed	All units Passed	All units Passed	Passed

(8) **Conclusions:**

Based on the non-clinical performance data performed comparing the Ensizor™ Endoscopic Scissors to the predicate device, it is concluded that the device is as safe, as effective, and performs as well as or better than the predicate device.